ACCOMPANYING LABELING: Booklet designated "Arkansas Mining Company Confidential Sales Information," leaflets designated "Comfort For Pains Like Those of Arthritis Rheumatism Now Mineral Baths in Your Own Home," booklets designated "Mineral Baths Arkansas Mining Company General Offices: Hot Springs, Ark.," and a display card designated "Enjoy Mineral Baths at Home from Hot Springs, Arkansas."

LIBELED: 10-23-57, Dist. Minn.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was effective in the treatment of arthritis, rheumatism, nervousness, skin and complexion disorders, chronic pains, and a rundown condition.

DISPOSITION: 12-4-57. Default—destruction.

DRUG ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH PACKAGING REQUIREMENTS OF AN OFFICIAL COMPENDIUM

5500. Water for injection. (F.D.C. No. 40324. S. No. 58-099 M.)

QUANTITY: 142 vials at Kansas City, Kans.

SHIPPED: 3-18-57, from Philadelphia, Pa., by Addison Laboratories.

LABEL IN PART: (Vial) "100 cc. Multiple Dose Vial Water For Injection A Ten Dose Container Pyrogen Free Contains: Phenol 0.5% Sterile * * * Physicians & Surgeons Supply, Wichita, Kansas."

RESULTS OF INVESTIGATION: *Water for injection* is a drug recognized by the United States Pharmacopeia. The U.S.P. monograph states under the heading "Packaging and storage,"—"Preserve Water for Injection in single-dose containers holding not more than 1,000 ml. or in multiple-dose containers holding not more than 30 ml. * * * Water for Injection containing no antibacterial agent may be packaged in a multiple-dose container of not greater than 100 ml. size, provided the package is marketed in combination with a medicinal preparation for parenteral administration for which it is to be the solvent."

Examination showed that each vial of the article was closed by a rubber stopper which could be readily penetrated by the ordinary hypodermic needle, thus the contents of the vial could be withdrawn without removal or destruction of the closure.

LIBELED: 6-14-57, Dist. Kans.

CHARGE: 502(g)—the article was a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when shipped, the article was not packaged as prescribed therein, since it was in a multiple dose container holding more than 30 ml. and it did not qualify for an exemption from that packaging provision.

DISPOSITION: 7-24-57. Default—destruction.

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5501–5520

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *June 26, 1959.*

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